

1615

Brobeck

ATTORNEYS AT LAW

BROBECK, PHLEGER & HARRISON LLP

1333 H STREET N.W.

SUITE 800

WASHINGTON, D.C. 20005

TELEPHONE 202.220.6000

FACSIMILE 202.220.5200

AUG 09 2001

RECEIVED

August 6, 2001



In re Patent Application of:

Ralph W. BLUME et al.

Application No.: 09/559,542

Filed: April 28, 2000

Title: GUAIFENESIN SUSTAINED RELEASE FORMULATION AND TABLETS

Attorney Docket No.: 031853.0003

#9

Group Art Unit: 1615

Examiner: C. Evans

Commissioner for Patents
Washington, D.C. 20231

Transmitted herewith is an amendment in the above-identified application. Fees have been calculated as shown below:

CLAIMS AS AMENDED						
	Claims Remaining After Amendment	Highest Number Previously Paid For	Extra	Rate		Amount
				Large Entity	Small Entity	
Number of Claims in Excess of 20	26	32	0	\$ 18.00	\$ 9.00	\$ 0.00
Independent Claims in Excess of 3	1	3	0	\$ 80.00	\$ 40.00	\$ 0.00
First Presentation of Multiple Dependent Claims				\$ 270.00	\$ 135.00	\$135.00
Extension Fee:						
a) One Month				\$ 110.00	\$ 55.00	\$ 0.00
b) Two Months				\$ 390.00	\$ 195.00	
c) Three Months				\$ 890.00	\$ 445.00	
d) Four Months				\$1390.00	\$ 695.00	
e) Five Months				\$1890.00	\$ 945.00	
Other: IDS after First Action						\$240.00
TOTAL FEE DUE						\$375.00

- ☐ No additional fee is required.
- ☐ A check in the amount of \$ _____ is attached.
- ☒ Charge \$ **375.00** to Deposit Account No. 50-1640.
- ☒ Charge any additional fees or credit any overpayment to Deposit Account No. 50-1640.

- Small Entity Status Claim:
- ☐ is attached.
- ☒ is of record in this application.

Respectfully submitted,

By: Rodger L. Tate
Rodger L. Tate
Registration No. 27,399

RLT/sdl

A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application Of:

Ralph W. BLUME et al.

Application Number: 09/559,542

Filed: April 28, 2000

For: GUAIFENESIN SUSTAINED RELEASE FORMULATION AND TABLETS

Group Art Unit: 1615

Examiner: C. Evans

RESPONSIVE AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the Office Action mailed May 4, 2001, please amend the above-captioned application as set forth below.

IN THE CLAIMS

Please cancel claims 1-32 and add the following new claims 33-55 provided in a clean format in accordance with 37 C.F.R. § 1.121 as follows:

Sub
R1
33. A modified release tablet having two portions, wherein a first portion comprises a first quantity of guaifenesin in an immediate release form which becomes fully bioavailable in the subject's stomach and a second portion comprises a second quantity of guaifenesin and a release-delaying matrix comprising a hydrophilic polymer and a water-insoluble polymer wherein the weight ratio of said hydrophilic polymer to said water-insoluble polymer is in the range of from about 1:1 to about 6.8:1, wherein said tablet demonstrates a C_{max} equivalent to an immediate release guaifenesin product and wherein said tablet also provides therapeutically effective bioavailability for at least twelve hours after dosing in a human subject according to serum analysis.

2 34. The modified release tablet of claim 33 wherein said hydrophilic polymer is selected from the group consisting of acacia, gum tragacanth, locust bean gum, guar gum, karaya gum, modified cellulosic, methylcellulose, hydroxymethylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethylcellulose, carboxymethylcellulose, agar,

03/03/2001 MWOLDR1 00000008 501640 09559542

01 FC:204 135.00 CH

TECH CENTER 1600/2900

AUG 09 2001

RECEIVED

[Handwritten signature]
8/6/01